

**JOB DESCRIPTION**

<b>Job Title</b>	<b>Clinical Operations Supervisor</b>
<b>Department</b>	Clinical Operations
<b>Major Responsibilities</b>	<ul style="list-style-type: none"> <li>• Conduct clinical trials in the absence of Clinical Study Manager as per written protocol and SOPs.</li> <li>• Communicate regularly with the Director, PI and Clinical Study Managers with regards to the progress and conduct of the study</li> <li>• Ensure smooth operation of in-house portions of the clinical trial</li> <li>• Hire, train, schedule and supervise Clinical Research Phlebotomists and Medical Assistants.</li> <li>• Manage direct reports. This includes but is not limited to: preparing and conducting performance appraisals for direct reports, carrying out progressive discipline as required, training and career development.</li> <li>• With Director of Clinical Development and Operations, develop hiring projections to ensure clinic growth is appropriate to achieve corporate goals.</li> <li>• Supervision of all clinical staff during the in-house portion of the clinical trial</li> <li>• Cooperate with Sponsors/Monitors during monitoring visits, audits and audit follow-up</li> <li>• Communicate, in a timely manner with Principal Investigator, Sub-Investigators and Clinical Study Coordinator with respect to subject issues; relay all medical and study related information obtained on volunteers/patients with regard to their involvement in the trials directly to the Investigator and ensure proper follow-up</li> <li>• Responsible for remaining current with regulatory requirements (TPD, FDA, EMEA, ICH, MHRA, etc.)</li> <li>• Assist with the maintenance, calibration and ensure proper operation, of clinical equipment according to manufacturer’s specifications and Acclaim Pharma Research SOPs</li> <li>• Cooperate with the Quality Assurance Division during Audits and Audit Follow-up</li> <li>• Work with the Quality Assurance group in the development/revision and implementation of Standard Operating Procedures as required</li> <li>• Ensure compliance with appropriate SOPs, GCP and ICH guidelines</li> <li>• Participate in training sessions</li> <li>• Execute other duties as may be required</li> </ul>
<b>Reports to</b>	Director of Clinical Development and Operations
<b>Communications</b>	<ul style="list-style-type: none"> <li>• Liaisons with the Director of Development and Operations, PI, QA, Clinical Study Manager</li> </ul>
<b>Requirements</b>	<ul style="list-style-type: none"> <li>• Completed postsecondary degree or diploma in a science or healthcare related discipline, or equivalent work experience</li> <li>• Flexible hours depending on business requirements.</li> <li>• Rotating shifts and weekend requirements.</li> <li>• 1-2 years work experience in a CRO (preferably in conducting Phase I /Bioequivalence clinical trials)</li> <li>• Excellent problem solving, communication, multitasking and interpersonal skills</li> <li>• Excellent in Microsoft word and excel. Solid conflict resolution skills</li> <li>• Good analytical and problem solving skills</li> <li>• Very organized, detail-oriented and able to multi-task</li> <li>• Good interpersonal and customer service skills</li> </ul>

This job description should not be constructed to imply that these requirements are the only duties, responsibilities and qualifications for this position. Employee may be required to follow any additional related instructions, acquire job skills and perform other related work if deemed necessary.